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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/467,368 | 12/20/1999 | PETER KAMP HANSEN | 4324.224-US | 2312 |

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NOVOZYMES NORTH AMERICA, INC.
500 FIFTH AVENUE
SUITE 1600
NEW YORK, NY 10110

| EXAMINER | |
|---|---|
| RAO, MANJUNATH N | |
| **ART UNIT** | **PAPER NUMBER** |
| 1652 | |

DATE MAILED: 07/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/467,368 | HANSEN ET AL. | |
| | Examiner | Art Unit | |
| | Manjunath N. Rao, Ph.D. | 1652 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *18 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *72-95* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *72-95* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

CONTINUED EXAMINATION UNDER 37 CFR 1.114 AFTER FINAL REJECTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12-23-04 and supplemental response on 3-18-05 has been entered.

Claims 72-90 are currently pending and are present for examination.

Applicants' arguments and the supplemental declaration filed on12-23-04 and 3-18-05, have been fully considered and are deemed to be persuasive to overcome the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 72-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lischnig et al. (Biotechnology letters, 1993, Vol. 15(4):411-414) or Gomes et al. (Appl. Microbiol.

Biotechnol., 1993, Vol. 39:700-707) and Haarasilta et al. (US 5,314,692, 5-24-1994), Hazlewood et al. (WO 93/25693, 12-23-1993).

Claims 72-90 of the instant application are drawn to an animal feed comprising a xylanase enzyme isolated from *Humicola lanuginosa* (*Syn., Thermomyces lanuginosus*) with characteristics as disclosed n claim 72 and a method of improving the growth of an animal by feeding said animal feed.

Lischnig et al. or Gomes et al. teach the isolation and characterization of the xylanase enzyme from *Humicola lanuginose.* Applicants also acknowledge (See page 1, line 28-33) such a teaching in the above references. However, the references do not teach the use of said enzyme for supplementing an animal feed or an animal feed comprising said enzyme.

The use of xylanases for supplementation of animal feeds has been known in the art for quite some time. The references of Hazlewood et al. and Haarasilta et al. teach the extensive use of xylanase enzymes in food and feed industry (see the entire reference of Hazlewood et al., specifically pages 20-23). Specifically Hazelwood et al. teach that chicks when fed feeds supplemented with xylanase improve in their weight gain. The reference teaches that the effects of undigested pentosans --which have been implicated for poor nutrient uptake and sticky droppings-- can be overcome by the use of feed supplemented with xylanase.

Therefore combining the teachings of the above references, it would have been obvious to one skilled in the art to use the knowledge existing in the field of enzyme purification, and recombinant techniques at the time the application was filed, to purify the thermostable xylanase taught by Lischnig et al. or Gomes et al. to homogeneity and use it for making an animal feed comprising said enzyme or make recombinant DNA or isolate polynucleotides that hybridize to

said recombinant DNA under the highly stringent conditions and isolate the encoded xylanase and use it for making an animal feed as claimed in claims 72-90. While the references may not teach the testing of the enzyme for residual activity at the temperatures claimed in the instant application, they all teach that the enzyme is thermostable. Furthermore, since the enzyme in the references has been isolated from the very same microorganism as that in the instant application, Examiner takes the position that the enzyme in the reference and the enzyme claimed in the instant application are one and the same and the thermostable characteristics and residual activity characteristics are all inherent features of the enzyme. One of ordinary skill in the art would have been motivated to do so as the xylanases taught in the above references are thermostable and therefore withstand the higher temperatures that may have to be used during the process of making, storing and transporting the feed. One of ordinary skill in the art would have a reasonable expectation of success since the art is rich in teachings regarding use of xylanase enzyme in the field of food and feed industry, and specifically Hazelwood et al. demonstrate such a use. Therefore Lischnig et al. or Gomes et al. in combination with Hazlewood et al. or Haarasilta et al. render claims 72-90 *prima facie* obvious to one or ordinary skill in the art.

In response to the previous Office action, applicants have again traversed the above rejection basically arguing that none of the cited references teach or suggest the use of thermostable xylanases in animal feed composition or that there would be any advantage to using a thermostable xylanase over a thermolabile xylanase in animal feed. Examiner respectfully disagrees with such an argument. While the references may not explicitly teach the advantages of using a thermostable enzyme over a thermolabile enzyme, such advantages would be readily obvious to those skilled in the art and Examiner has enumerated such advantages in his rejection.

Therefore, the teachings by the reference of very same xylanase and the teachings for use of xylanases in general in animal feeds are enough to render the above invention *prima facie* obvious to those skilled in the art.

Applicants next argue against the rejection using the doctrine of " surprising and unexpected results". Applicants refer to a comparative experiment in which they compare a commercial enzyme with that of the invention and argue that the animal feed comprising the commercial enzyme at a dose of 400 FXU/kg gave a % fat digestion in the range of 72.1-74.3, while the animal feed comprising the present invention gave a % fat digestion in the range of 72.1-74.3 even though the xylanase was dosed at 100 or 200 FXU/kg and therefore the instant invention demonstrated superior property not predicted by prior art and that these results are surprising and unexpected. Examiner finds it difficult to accept the above results as surprising or unexpected. This is because it would be well within the level of skill of those practicing the art that decrease in viscosity will lead to better absorption and better digestion of feed ingredients. As pointed by the applicants themselves, it was well known in the art through the teachings of Anison et al. that high viscosity reduces the apparent metabolizable energy of feed ingredients. Therefore, this aspect of the invention cannot be considered as surprising or unexpected of the xylanase enzyme in the feed.

Examiner has considered the supplemental Declaration of Dan Patterson submitted by the applicant under 37 CFR 1.132. The declaration again describes the experiments comparing the metabolizing energy available and the FCR values of two groups of test animals, wherein one group was fed an animal feed comprising the invention and the other group was fed an animal feed comprising the control xylanase enzyme isolated from *Aspergillus* and concludes

that animal feed comprising the invention results in better feed utilization that is statistically significant when compared with an animal feed comprising the xylanase from *Aspergillus*. In this supplemental declaration, Mr. Pettersson argues that the data obtained is statistically significant, specifically with respect to the Feed Conversion Ratio or the FCR. Mr. Pettersson argues that the FCR value for the experiment in which animals were fed a feed with "no enzymes" was 2.16, 1.97 for the experiment using a feed comprising xylanase from *T.lanuginosus* (thermostable) and 2.02 for the experiment using a feed comprising a xylanase enzyme from *Aspergillus aculateus* (not thermostable). In summary Mr. Pettersson is arguing that the value 2.02 obtained for the feed comprising xylanase from *A.aculateus* is less significant than the value 1.97 obtained for the feed comprising the xylanase from *T.lanuginosus*. Such a declaration is very hard for the Examiner to accept since it defies scientific explanation. It is highly perplexing to the Examiner as to how the two values 2.02 and 1.97 (differing by only 0.05) can be considered statistically significant without any supporting data such as sample size, degrees of freedom or even the bare minimum of a "p" value for the data obtained. Actually, the values appear to be within the experimental error of an experiment involving animals. All that applicants have done is to come out with a supplemental declaration declaring that the experimental results are statistically significant in response to the Examiner's previous comments that in view of lack of a showing that a statistically significant difference exists in the results between the feed comprising the instant enzyme and the feed comprising the control enzyme, Examiner has concluded that the results are neither surprising nor unexpected findings. However, Examiner still takes the position that the experimental data provided does not

overwhelmingly point towards a surprising and unexpected results and therefore continues to maintain the rejection.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

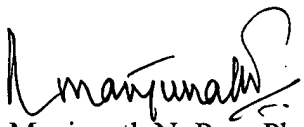
Claims 72-90 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,245,546 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to the same xylanase enzyme encoded by the same polynucleotide (nucleotides 31-705 of SEQ ID NO:1) and a premix and a process of making animal feed comprising the above xylanase enzyme.

In response to the above rejection in the previous Office action, applicants have responded that they will submit a Terminal Disclaimer upon the indication of allowable subject matter. Examiner maintains the rejection for reasons of record.

***Conclusion***

None of the claims are allowable.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 571-272-0939. The Examiner can normally be reached on 7.00 a.m. to 3.30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



Manjunath N. Rao, Ph.D.
Primary Examiner
Art Unit 1652

July 5, 2005